

Remarks

Applicant has carefully reviewed the grounds for rejection under 35USC 103 which are hereby traversed.

In the preliminary amendment now on file, the invention was explained in terms of the importance of not only the components but their order of use. The citation of in re Papesch is noted and its holding is not disputed. That case however is not applicable with respect to the present invention as the final product, contrary to the position taken by the Examiner is not obvious and certainly not suggested by the references cited by the Examiner.

The key to the present invention lies in component (b) of claim 25. The intent of both Klocker and the present inventor is the same, namely to administer a water soluble bioactive in a non aqueous medium. Klocker speaks of solutions and suspensions, Applicant of solutions only. Klocker exemplifies suspensions only, at Col 5 lines 25-40 (not 5-22) he indulges in some wishful disclosure. There is no specific teaching that this approach is operative. Applicant, who has over 40 years of experience in formulation, tried this approach in numerous experiments leading up to the present invention and found that it did not work-

It should be noted that Klocker does not attempt to create a solution, he merely suspends the bioactive in the carrier, which is of course the same as applicant's carrier.

As noted in arguments submitted in 10/406,869 (which will become abandoned by non reponse) Halswander is not properly citable as it comes from a non related art namely aqueous nasal sprays. Glycols are disclosed as moisturizers. There is no teaching of them as solvents for the bioactives. The use of glycols as initial solvents for the bioactives does not appear in any of the cited references.

Section (d) of claim 25 specifically requires the glycol to be one in which the bioactive is soluble. The solution of the bioactive in the relatively small amount of glycol does not make it soluble in the carrier. As stated previously, Applicant tried to use the conventional approach of using solvating agents such as those listed by Klocker, but was not successful.

The Examiner states that since Halswanger teaches the glycols used by applicant (again for a totally different purpose) “it follows” that the glycols are also soluble in the ester of 25 (b). The mutual solubility is indeed a fact but this does not “follow” from any disclosure, specific or implied in any of the references. The Examiners logic chain also fails here.

Further, there is not the breath of a suggestion that because the bioactive which is dissolved in the glycol, which is dissolved in the ester would stay in solution when mixed with the carrier. The science of co-solvation is complex and not predictable.

It is again stated that the possible moisturization effect of the glycol is irrelevant, its importance lies in its totally unsuggested function as a primary solvent in a three solvent chain.

The essential second link in this chain is the ester, whose importance is nowhere suggested or disclosed.

Omori’s teaching of the use of lactate esters is not disputed, however this has nothing to do with their use in the solution sequence which is the basis of the present invention

Applicants traverse the applicability of In re Rubin. It is the core of the present invention that the order of addition is critical as has been shown in Example 1 of Applicant’s declaration presently on file in this application.

Since applicant has clearly shown that the product is not obvious in view of the art the citation of In re Thorpe is not relevant and any implication of its relevance is traversed.

Applicant sees no reason to discuss the Examiners arguments set forth from the last paragraph on page 10 of the Official Action through page 12 first complete paragraph thereof, as the arguments there advanced are based on the Examiner’s positions which have been shown above to be inapposite.

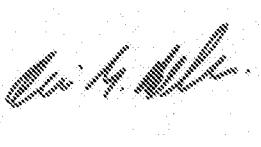
In View of Applicant’s intention to abandon SN 10/406 865, there appears to be no

need to file a terminal disclaimer. However if it will expedite issuance of this application, such a disclaimer will be filed on telephonic request.

In view of the foregoing comments and amendments, applicant respectfully submits that this application is in condition for allowance and prompt passage to issue is respectfully solicited.

Respectfully submitted

The Behr Office

By 

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